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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1639

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/612,298

Applicant(s)

ANDERSON, BYRON E.

Examiner

Christopher M. Gross

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 10-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9 and 43-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/11/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Responsive to communications entered 4/10/2006. The Examiner on the instant case has changed. See contact information below. Claims 1-45 are pending. Claims 1-4, 10-42 are withdrawn. Claims 5-9, 43-45 are examined herein.

#### ***Election/Restrictions***

Applicant's election with traverse of group II (claims 5-9, 43-45) in the reply filed on 4/10/2006 is acknowledged. The traversal is on the ground(s) that methods and compositions can be searched without any serious burden on the Office. This is not found persuasive because a search concerning the claimed methods, such as reducing toxicity per group V or inhibiting ant-Ley/H per group IX, etc. would not be coextensive with a search for the D-peptide library per group II and vice versa.

Moreover, a search of each of the methods and compositions would require different key word and sequence searches in different patent, non-patent literature and require, at least, specific searches for particular method steps not required in the structure based search for the compositions. These searches would then require subsequent in-depth analysis of all relevant prior art literature, placing a serious and undue burden on the Office in terms of both search and examination if the methods and compositions are kept together.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-4, 10-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/11/2006.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged: this application claims priority to provisional application 60/394176 (filed 7/3/2002) as indicated on the oath.

***Information Disclosure Statement***

The information disclosure statement filed 4/11/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein regarding WO 01/11360 has not been considered.

***Claim Objections***

Claims 44 and 45 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 44 and 45 are drawn to a non-elected invention (i.e. claim 31).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9, 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term "D-peptide(s)" in claims 5-9,43 is used by the claim(s) to mean a "peptide containing all D amino acids", while the accepted meaning of 'D' concerns the stereochemistry of one residue, not the entire sequence. The term is indefinite because the specification does not clearly redefine the term.

Claims 44 and 45 each recite the limitation "the library" in line 1. There is insufficient antecedent basis for this limitation in the claim. Moreover, the Markush group set forth in claim 31 consists of two separate singular species: Xaa<sub>1</sub>YYFF and Xaa<sub>1</sub>FYFF. Said Markush group(s) do not constitute the plurality of species necessary for a library.

Claim 44 recites vague and indefinite language in the “solid support is attached to a bead” To one of skill in the art, a bead *is* a solid support, thus the claim ambiguous. As currently written, the metes and bounds of the claim is unascertainable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Dooley et al (1994 Science 266:2019-2022).

The claimed invention is drawn to a library comprising a plurality of D-peptides, wherein each D-peptide comprises from three to seven D-amino acid residues, wherein at least 25% of the D-peptides comprise at least three amino acid residues independently selected from the group consisting of D-tryptophan, D-tyrosine, and D-phenylalanine. Claims 6-9 represent variations thereof.

Dooley et al teach, throughout the document and especially the abstract and table 1, column c, the preparation of libraries of D-amino acid containing heptapeptides (7 residues). In particular, Dooley et al teach a Ac-rtfwyxx-NH<sub>2</sub> library, which contains fixed residues including D-tryptophan (w), D-tyrosine (y), and D-phenylalanine (f) in 100% of the species in the library. Said library of Dooley et al reads on all the limitations of claims 5 and 6.

In the library according to Dooley et al, the two random residues (x) provide 400 peptide species (20 x 20), thus reading on at least 50, 10 or 5 D-peptides per instant claims 9,8, and 7 respectively.

Claims 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinilla et al (1998 J. Mol Biol 283:1013-1025 – IDS entry 4/11/2006).

Pinilla et al teach, throughout the document and especially table 1, an all-D amino acid containing hexapeptide library. In particular, Pinilla et al teach a Ac-yryxxx-NH<sub>2</sub> library, which contains two fixed D-tyrosine (y) residues plus three random positions (including D-tyrosine), such that 74% (20 of 27) of the species in the library have three D-tyrosine residues. The library of Panilla reads on the limitations set forth in claims 5 and 6.

The library of Panilla consists of 27 total peptide species which reads on the five and ten peptides of claims 7 and 8, respectively.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9,43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of **Dooley et al** (1994 Science 266:2019-2022) or **Pinilla et al** (1998 J. Mol

Biol. 283:1013-1025 – IDS entry 4/11/2006) in view of either of **Lam et al** (1991 Nature 354:82-84) or **Lebl et al** (1995 Biopolymers 37: 177-198 – IDS entry 4/11/2006).

The claimed invention is drawn to a library comprising a plurality of D-peptides, wherein each D-peptide comprises from three to seven D-amino acid residues, wherein at least 25% of the D-peptides comprise at least three amino acid residues independently selected from the group consisting of D-tryptophan, D-tyrosine, and D-phenylalanine. Claims 6-9, 43-44 represent variations thereof.

**Dooley et al** teach, throughout the document and especially the abstract and table 1, column c, the preparation of libraries of D-amino acid containing heptapeptides (7 residues). In particular, Dooley et al teach a Ac-rtfwyxx-NH<sub>2</sub> library, which contains fixed residues including D-tryptophan (w), D-tyrosine (y), and D-phenylalanine (f) in 100% of the species in the library. Said library of Dooley et al is taken to meet all the limitations of claims 5 and 6.

In the library according to Dooley et al, the two random residues (x) provide 400 peptide species ( $20^2$ ), thus is taken as providing at least 50, 10 or 5 D-peptides per instant claims 9, 8, and 7 respectively.

**Pinilla et al** teach, throughout the document and especially table 1, an all-D amino acid containing hexapeptide library. In particular, Pinilla et al teach a Ac-yryxxx-NH<sub>2</sub> library, which contains two fixed D-tyrosine (y) residues plus three random positions (including D-tyrosine), such that 74% (20 of 27) of the species in the library have three D-tyrosine residues. The library of Panilla is taken to provide all the limitations set forth in claims 5 and 6.



The library of Panilla et al consists of 27 total peptide species which is taken as providing the five and ten species set forth in claims 7 and 8, respectively.

Neither Dooley or Pinilla et al teach the D-Peptide(s) on a solid support beads, however.

Both **Lam et al** and **Lebl et al**, throughout the documents, teach the preparation of peptide libraries on solid support beads.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to prepare the D-amino acid containing peptide libraries of Dooley et al or Pinilla et al on solid support beads per Lam et al or Lebl et al.

One of ordinary skill in the art would have been motivated to make the D-amino acid containing peptide libraries of Dooley et al or Pinilla et al on solid support beads per Lam et al or Lebl et al. because it would have simplified handling and it would have been faster in identifying potential ligands, as noted by Lam et al on page 83.

One of ordinary skill in the art could have used the D-amino acid containing peptide libraries of Dooley et al or Pinilla et al on solid support beads per Lam et al or Lebl et al. with a reasonable expectation of success as Lam and Lebl provide many successful examples.

Claims 5-9 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dooley et al** (1994 Science 266:2019-2022) in view of **Satoh et al** (1998 Analytical Biochemistry 260:96-102).

**Dooley et al** is relied on as above. Furthermore, Dooley et al teach in table 1, column a, a Ac-ryxxxx-NH<sub>2</sub> library, which absent evidence to the contrary, contains species meeting all the criteria set forth in claim 45.

Dooley et al do not teach each peptide attached to a microtiter plate, however.

**Satoh et al** teach, throughout the document and especially figure 1, the immobilization of peptides on a 96-well microtiter plates coated with methyl vinyl ether-maleic anhydride.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to immobilize the D-amino acid containing peptide libraries of Dooley et al on a microtiter plate coated with methyl vinyl ether-maleic anhydride per Satoh et al.

One of ordinary skill in the art would have been motivated to make the D-amino acid containing peptide libraries of Dooley et al immobilized on a microtiterplate coated with methyl vinyl ether-maleic anhydride per Satoh et al because it would have improved detection, as noted by Satoh et al on page 100, second paragraph.

One of ordinary skill in the art could have used the D-amino acid containing peptide libraries of Dooley et al with the microtiterplate coated with methyl vinyl ether-maleic anhydride per Satoh et al with a reasonable expectation of success as Satoh et al provide many successful examples.

### **Conclusion**

Claims 5-9, 43-45 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg



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PATENT EXAMINER